CDRH Final Guidance 2-Page Cover Sheet

Guidance for Industry

In Vitro Diagnostic Urea Nitrogen Test System

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Chemistry Toxicology and Hematology Branch
Division of Clinical Laboratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Joseph L. Hackett, Ph.D., Division of Clinical Laboratory Devices, HFZ-440, 9200 Corporate Blvd, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Joseph L. Hackett, Ph.D., at 301 594-3084.

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Guidance Document

Device: In Vitro Diagnostic Urea Nitrogen Test System

I. Device Description

Common Name (s): Urea Nitrogen Test System

Class: II

Classification Panel: Clinical Chemistry (75)

Product Codes:

CDL, Berthelot Indophenol, Urea Nitrogen
LFP, Conductivity Rate, Urea Nitrogen
CDS, Diacetyl-Monoxime, Urea Nitrogen
JGZ, O-Phthalaldehyde, Urea Nitrogen
CDQ, Urease and Glutamic Dehydrogenase, Urea Nitrogen
CDN, Urease, Photometric, Urea Nitrogen

Regulation numbers,: 21 CFR 862.1770

A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood serum, plasma, and urine.

II. Indications for Use

Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases. The intended patient population may be adult, pediatric, and neonatal, while the environment of use may be a hospital (e.g., respiratory care or laboratory department), urgent care situations (e.g., intensive care unit, surgery, emergency department), or bedside/near patient care situations.

III. Specific Performance Characteristics

A. PreClinical/Laboratory/In Vitro Studies

The following eight performance characteristics (#1 Method Comparison - #8 Expected Values) should be included in the submission. Data should be provided that supports the use of the device with the specimen type(s) that are claimed to be appropriate for analysis:

1. Method Comparison
    - -slope, intercept
    - -correlation coefficient
    - -range of samples tested
    - - standard error of the estimate
    - -bias and bias plot
    - -number of samples tested
    - -plot of the data

2. Precision
    - -within-run (assay, and
    - -between-run (assay), or
    - -total
    - -mean(s), standard deviation (s), and coefficient(s) of variation

3. Linearity
    - -recovery, dilution, etc.

4. Sensitivity
    - -minimum detection limit, or
    - -analytical sensitivity

5. Interferences
    - -endogenous, e.g., bilirubin, hemoglobin, lipids, etc.
    - -exogenous, e.g., drugs, anticoagulants, etc.

6. Stability Summary
    - -calibration interval
    - -quality control interval
    - -quality control materials
    - -calibration materials

7. Software
    - -validation information
    - -certification information

8. Expected Values
    - -literature reference (s), reference interval, or
    - -population study, reference interval,
    - -medical decision point(s) and/or
    - -critical decision point(s)

B. Clinical Studies

A method comparison study as described above, comparing performance with that of the predicate device as well as an appropriate reference method should be conducted to demonstrate substantial equivalence. A statistically significant sample of patients from a population representing the proposed intended use should be included in the study, spanning the appropriate assay range.

C. Total Measurement Error at selected decision points should be calculated and reported.

IV Labeling Considerations:

Refer to 21 CFR 809.10.

Other: For a multi-purpose instrument used for diagnostic purposes refer to 21 CFR 809.10 (b) (1),(2),(6),(14),and (15).

Checklist

Instructions: Use this checklist for premarket notification for Urea Nitrogen Test System as a guide in preparing your submission.

Truthful and Accurate statement verbatim as per 21 CFR 807.87(j).	
510(k) summary or statement per 21 CFR 807.92 or 21 CFR 807.93 respectively.	
Indications for use on a separate page.	
Labeling for in vitro diagnostic products (21 CFR 809.10 (b)	
Pre-Clinical Data:	
Interference Studies	
Linearity Studies	
Precision studies at medical decision levels	
Clinical Data (method comparison)	

REFERENCES:

Methodologies to assist sponsors in establishing the specific performance characteristics addressed in part III of this document may be obtained using NCCLS documents or one of the following references:

Carey RN and Garber CC: Evaluation of Methods in Clinical Chemistry - theory, analysis, and correlation; Kaplan LA and Pesce AJ (eds), CV Mosby Company, St. Louis, 1984.

Koch DD and Peters T: Selection and Evaluation of Methods in Tietz Textbook of Clinical Chemistry (Burtis CA and Ashwood ER, WKB Saunders Co, Philadelphia, 1994.